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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,618	04/20/2004	Robert E. Dudley	04274661	7286

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EXAMINER	
JEAN-LOUIS, SAMIRA JM	

ART UNIT	PAPER NUMBER
1617	

NOTIFICATION DATE	DELIVERY MODE
02/05/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@mayerbrown.com

Office Action Summary	Application No.	Applicant(s)	
	10/829,618	DUDLEY ET AL.	
	Examiner	Art Unit	
	SAMIRA JEAN-LOUIS	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6-9,11-18 and 22-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 6-9, 11-18, and 22-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

This Office Action is in response to the amendment submitted on 11/13/2008. Claims 1, 6-9, 11-18, and 22-28 are pending in the applications, with claims 2-5, 10, 19-21, and 29-42 having being cancelled. Accordingly, claims 1, 6-9, 11-18, and 22-28 are being examined on the merits herein.

Receipt of the aforementioned amended claims is acknowledged and has been entered.

Applicant's traversal of the rejection of claims 1-41 under 35 U.S.C. § 112, first paragraph has been fully considered. Given that applicant has deleted the term "preventing" and amended the claims, such rejection is now moot. Consequently, the rejection of claims 1-41 under 35 U.S.C. § 112, first paragraph is hereby withdrawn.

Applicant's traversal of the rejection of claims 2-28 and 30-31 under 35 U.S.C. § 112, first paragraph has been fully considered. Given that applicant has cancelled claims 2-5, 19-21, and 30-31 and amended the remaining claims, such rejection is now moot. Consequently, the rejection of claims 2-28 and 30-31 under 35 U.S.C. § 112, first paragraph is hereby withdrawn.

Applicant's arguments against the 35 U.S.C § 102(e) rejection of claims 1-11, 15-23, 25-38, and 41 over Dudley et al. has been fully considered and is found persuasive.

Given that Dudley et al. share the same inventive entity, such reference is unavailable as prior art under 102 (e). Thus, the aforementioned rejection is hereby withdrawn.

Applicant's traversal over the rejection of claims 24 and 30-31 under 35 U.S.C. § 103 (a) has again been fully considered and is found persuasive. Given that the primary reference Dudley et al. is not available as prior art reference due to common inventive entity, such rejection is now moot. Consequently, the aforementioned rejection is hereby withdrawn.

For the foregoing reasons, the rejections of record are hereby withdrawn. The following 103 (a) Non-Final rejections are being made.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **(see M.P.E.P 608.01 (k))**.

Claim 8 is particularly vague and indefinite given that applicant is claiming "carboxypolyniethylene" as a type of polyacrylic acid **(in sentence 2 of claim 8)** and yet no such compound exists. Given that applicant did not particularly point out what

particular polyacrylic acid is encompassed by the invention, one of ordinary skill in the art would not be able to fully ascertain the metes and bounds of the aforementioned claim.

As a result of the above inconsistencies, the aforementioned claim is unable to be examined as disclosed given that the scope of the claimed subject matter would not be able to be determined by one of ordinary skill in the art. However, for the purpose of compact prosecution, Examiner will construe that the stated species of polyacrylic acid set forth in the claim is carboxypolymethylene.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 6-9, 11-18, and 22-28 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Dudley (US 2003/0022877 A1) in view of Applicant's admitted prior art.

Dudley teaches methods, kits with instructions, and compositions for treating or reducing the risk of developing a testosterone deficiency including conditions such as

decreased libido (see pg. 8, paragraph 0061) comprising testosterone, one or more lower alcohols, such as ethanol or isopropanol, a penetration enhancing agent, a thickener, and water (instant claims 1 and 24; see abstract. pg. 3, paragraph 0024 and pg. 8, paragraph 0061 and 0063). Dudley also teaches that such composition can be formulated as a hydroalcoholic gel (see pg. 3, paragraph 0024). The method comprises administering an amount of a composition to an area of skin of the subject , which delivers a therapeutically effective amount of testosterone to the blood serum of the subject wherein the testosterone comprises about 0.1% to about 10% testosterone, about 0.1% to about 5% isopropyl myristate, about 0.1% to about 5% gelling agent (i.e. thickening agent), and about 30% to about 95% alcohol selected from the group consisting of ethanol or isopropanol (instant claims 1, 6-7, and 9; see pg. 4, paragraph 0027). Dudley further teaches that the composition is capable of releasing the testosterone to the skin at a rate and duration that raises testosterone blood serum concentration to at least about 3 pg testosterone/ml (i.e. 300 pg/dL) within about 24 hours after administration (see pg. 4, paragraph 0027 and pg. 18, claim 1). As for the gelling agent, Dudley teaches the use of polyacrylic acid (including carbopol (i.e. carboxymethylene; instant claim 8; see pg. 7, paragraph 0056) or carboxymethylcellulose wherein the preferred amount is added in an amount of about 1% by weight to the composition (instant claims 6-7; see pg. 4, paragraph 0029). According to Dudley, the composition weight is less than or equal to 100 g or about 0.1 g to about a 10 g dose (instant claim 18), but preferably from about 1g to about 10 g, or about 2.5 g to about 7.5 (instant claims 11-14; see pg. 4, paragraph 0030). In

particular, Dudley teaches that 0.1g/day of the composition to the skin leads to an increase of at least about 5 ng/dl in serum testosterone concentration in the subject (instant claim 17) and Dudley further demonstrated that a testosterone dose of 0.5 g testosterone can deliver approximately 300 µg of testosterone/day (see pg. 4, paragraph 0032 and pg. 6, paragraphs 0047-0048 and table 4). Dudley et al. also teach that the testosterone gel composition can be provided in one or more packets having a polyethylene liner between the composition and inner surface of the packet, or formulated as a kit, and administered once , twice, or three times a day for 30 days (instant claims 22-24 and 26-28; see pg. 4, paragraphs 0034-0036 and pg. 17, paragraphs 0125 and 0128).

Dudley does not particularly teach treatment of a depressive disorder. Moreover, Dudley does not teach that administration of his composition will result in a total serum concentration of at least about 490 ng/dL to about 860 ng/dL or that the pretreatment serum testosterone concentration is less than 300 ng/dL.

Given that applicant stated on the record in the specification (pg. 40) that depressive disorder includes conditions such as decreased libido, and Dudley teaches that testosterone deficient disorders include conditions such as decreased libido, the Examiner contends that one of ordinary skill in the art would have found it obvious to administer the composition of Dudley to treat depressive disorder in light of applicant's disclosure.

Moreover, one of ordinary skill in the art would have found it obvious optimize the concentration of testosterone in the composition of Dudley in order to achieve the desired testosterone serum concentration given that Dudley teaches that his composition is capable of releasing testosterone to the skin at a rate that raises testosterone blood serum concentration to at least 3pg/ml (i.e. 300 pg/dL; see pg. 18, claim 1) and in light of the disclosure in Dudley where he teaches that administration of 0.5 g of testosterone resulted in an amount of approximately 300 µg of testosterone per day. Furthermore, Dudley teaches that the concentration of the ingredients in the composition can vary (see pg. 6, paragraph 0050) and therefore varying the concentration of testosterone would necessarily affect the testosterone concentration being released. Moreover, it is well within the purview of a skilled artisan to vary the concentration of the ingredients of Dudley et al. if an increased release rate is desired in a subject.

As for applicant's claim limitation that the subject has a pretreatment serum testosterone concentration less than about 300 ng/dL, it is the Examiner's contention that one of ordinary skill in the art would have found it obvious to test a subject and determine the pre-treatment serum testosterone level in such subject and consequently determine if such subject is in need of treatment.

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to vary the constituents of the composition of Dudley since Dudley et al. teaches that the ingredients in his composition may be varied.

Moreover, it is generally noted that differences in concentration do not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Given that applicant did not point out the criticality of specific ranges or percentages of the invention, it is concluded that the normal desire of scientists or artisans to improve upon what is already generally known would provide the motivation to determine where in a disclosed set of ranges is the optimum combination of percentages.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-6 PM EST M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. L. /

Examiner, Art Unit 1617

01/23/2009

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617